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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,730	10/19/2001	Paul Arthur Mason	10071-018-999	9664

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,730	MASON, PAUL ARTHUR	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2005* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,12-16,22,24-27,55,56 and 59-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,12-16,22,24-27,55,56 and 59-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *08/26/05* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for extension of time, both filed 07/55/2005; and IDS, filed 09/09/2005.

Claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 are included in the prosecution.

Claim Rejections - 35 USC § 103

1. Claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,469,227 (227) in view of US 5,143,071('071).

US '227 teaches a non-occlusive adhesive skin patch used to relieve topical discomfort (abstract; col.2, lines 5-8). The patch comprises a breathable backing of polyester coated with a therapeutic formulation (col.3, lines 7-16, 35-36, 42, 50-56). The patch is packaged (col.4, line 1; col.18, lines 45-47). The therapeutic formulation is hydrogel that comprises local anesthetic such as lidocaine, and polymer such as polyvinyl pyrrolidone (col.4, lines 13-15, 28, 45; col.7, lines 1-2; col.11, lines 43-45). The patch further comprises alcohol, which reads on the preservative (col.6, line 6). The lidocaine is present in that the amount of 0.5-4% (col.5, lines 13-15).

US '227 does not teach that the patch is sterile, the amount of PVP, the patch is sterile or the specific preservatives.

The specific preservatives do not impart patentability to the claims, absent evidence to the contrary.

US '071 teaches a hydrogel comprising from 5-35% PVP (abstract; col.9, lines 54-47). The hydrogel further comprises anesthetic and preservative such as paraben esters and phenoxyethanol (col.15, lines 60-65; col.15, lines 4-7; col.26, lines 35-59). The hydrogel is used for skin bandage and provided sterile and packaged (col.12, lines 14-29). The PVP hydrogel layer is non-stingy, more cohesive than adhesive and less aggressive to the patient skin (col.9, lines 2-5; col.10, lines 39-40).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a patch for anesthetizing the skin comprising layer of PVP hydrogel, lidocaine and preservative on a breathable backing as disclosed by US '227 and select the amount of PVP between 5-35% as disclosed by US '071, motivated by the teaching of US '071 that the PVP hydrogel layer comprising that amount is non-stingy, more cohesive than adhesive and less aggressive to the patient skin, with reasonable expectation of the delivered patch to ameliorate pain at the site of application without irritating the skin.

2. Claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over PGBP 2003/0027833 ('833) in view of US '071.

PGPB '833 teaches a method and a delivery system for administration of at least one local anesthetics agent to a patient by applying the delivery system to the skin (abstract; page 2, 0017, 0019). The drug delivery device comprises a backing layer

laminated to a drug reservoir (page 2, 0023; page 8, 0088). The reservoir comprises a hydrogel comprising hydrophilic polymers comprising polyvinyl pyrrolidone (page 6, 0070, 0071; page 8, 0086; page 9, 0091). The reservoir comprises the local anesthetic and a preservative (page 8, 0083). The backing layer is preferably breathable and made of polyester or polyether (page 9, 0092). The preferred local anesthetic is lidocaine (page 4, 0048).

PGPB '833 does not teach the patch is sterile and packaged, or the amount of the anesthetic and PVP, or the specific preservatives.

The specific preservatives do not impart patentability to the claims, absent evidence to the contrary.

The amounts of different ingredients and specific species are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

US '071 teaches a hydrogel comprising from 5-35% PVP (abstract; col.9, lines 54-47). The hydrogel further comprises anesthetic and preservative such as paraben esters and phenoxyethanol (col.15, lines 60-65; col.15, lines 4-7; col.26, lines 35-59). The hydrogel is used for skin bandage and provided sterile and packaged (col.12, lines 14-29). The PVP hydrogel layer is non-stingy, more cohesive than adhesive and less aggressive to the patient skin (col.9, lines 2-5; col.10, lines 39-40).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a patch for anesthetizing the skin comprising layer of

PVP hydrogel, lidocaine and preservative on a breathable backing as disclosed by US '833 and select the amount of the anesthetic according to specific patient need and the amount of PVP between 5-35% as disclosed by US '071, motivated by the teaching of US '071 that the PVP hydrogel layer comprising that amount is non-stingy, more cohesive than adhesive and less aggressive to the patient skin, with reasonable expectation of the delivered patch to ameliorate pain at the site of application without irritating the skin.

Response to Arguments

3. Applicant's arguments filed 07/05/2005 have been fully considered but they are not persuasive. Applicant traverse these rejections by arguing that no suggestion to one of ordinary skill in the art to use the cross-linked PVP hydrogel with the occlusive patch disclosed by US '227 or with the composition of US '833 because US '227 and US '833 listed PVP within long list and not as a preferred polymer. US '227 and US '833 do not mention desirability to use PVP or cross-linked PVP. US '071 is in a different field of endeavor than US '227 and US '833, and one of ordinary skill in the art would not have been motivated to look in US '071 to supply the alleged deficiencies in US '227 or US '833. The rejection of the claims over US '227 or US '833 each combined with US '071 is based on the use of impermissible hindsight. There is no expectation of success in combining US '227 or US '833 with US '071 that disclosed cross-linked PVP hydrogel and the examiner conclusory statement cannot form basis for prima facie case of obviousness.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one having ordinary skill in the art would have been motivated to use the cross-linked hydrogel disclosed by US '071 instead of the hydrogel disclosed by any of US '227 or US '833 because US '071 teaches that the cross-linked PVP hydrogel layer is non-stingy, more cohesive than adhesive and less aggressive to the patient skin. The disclosed examples and preferred embodiment of the prior art do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

In response to applicant's argument that US '071 is in different field of endeavor than US '227 and US '833, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24

USPQ2d 1443 (Fed. Cir. 1992). In this case, US '071 disclosed cross-linked PVP hydrogel used in skin devices to administer drugs transdermally, and US '227 and US '833 are in the field of transdermal drug delivery area also. Furthermore, as set forth, US '071 provided motivation and advantage for using cross-linked PVP hydrogel, and one having ordinary skill in the art would have been motivated to replace the hydrogel of the skin patch disclosed by US '227 or US '833 by the cross-linked non-stingy cohesive PVP hydrogel with reasonable expectation of having a patch to ameliorate pain at the site of application without irritating the skin comprising the non-stingy cohesive cross-linked PVP and local anesthetic.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not

necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). Therefore, the invention as a whole is disclosed by the combined teachings of US '227 and US '071 and a *prima facie* case of obviousness has been established.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615
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